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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/973,088	Applicant(s) CONNETT-PORCEDDU ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-43 and 45-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-43 and 45-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

RCE Acknowledgment

1. The request filed on April 1, 2005 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/973,088 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1-9, 11-43 and 45-62 are pending and are examined in the present office action.

Specification

3. On page 26, paragraph 73, the specification is objected to because the last sentence is incomplete and does not end with a period.

Claim Rejections - 35 USC § 112

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9, 11-43 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims have been amended to recite “and an osmoticum”. Applicants fail to point to support for the phrase in the instant specification. Upon a cursory search of the specification, support could not be found. Applicants are required to point to support for “and an osmoticum” or to amend the claims to delete the NEW MATTER.

Scope of Enablement

5. Claims 1-9, 11-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* comprising co-cultivating pine cells of the *Pinus* subgenus with *Agrobacterium* for *Agrobacterium* transformation, washing said pine cells subsequent to infection with *Agrobacterium* with culture medium comprising inorganic salts, vitamins, amino acids, inositol, casein hydrolysate, sucrose, and auxin, cytokinin, or abscisic acid or combinations of the hormones, followed by a step to eradicate the *Agrobacterium* using said medium which further comprises an eradicator of *Agrobacterium* and abscisic acid (ABA), followed by a repetition of washing the cells in the above medium and collecting the cells on a support membrane, culturing the cells on a support membrane which is placed over a medium comprising the above constituents and further comprising a selection agent and ABA whereby the transformed cells are selected, growing the selected cells on a support membrane which is placed on a medium comprising said constituents and further comprising ABA wherein the cells develop into somatic embryos and followed by germinating the somatic embryos on medium comprising ABA, does not reasonably provide enablement for claims drawn to said method in which the above medium is not used, or an eradication step is not included, or ABA is not

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included in any of the steps recited above, or the cells are not washed in a medium comprising the above recited constituents in between the Agrobacterium infection step, the Agrobacterium eradication step, the selection step, or growing the transformed pine cells into transformed somatic embryo step, wherein the cells or embryos are collected on a support membrane which is placed over medium comprising said constituents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* comprising incubating the cells with Agrobacterium, washing cells with a liquid culture medium comprising nutrients and an osmoticum, selecting transformed cells, culturing said transformed cells to produce transgenic somatic embryos and germinating said embryos to produce plants, or wherein the cells are washed and recovered subsequent to Agrobacterium infection using a liquid wash medium and collecting said cells on a support membrane and washing and collecting said cells a number of times and varying the length of the

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wash step, or wherein the selection step is performed by placing said cells on a support membrane which is placed on medium containing a selection agent, or wherein the Agrobacterium cells are eradicated after infecting the pine cells by culturing the cells that have been infected by Agrobacterium on a support membrane which is placed on a medium containing an eradicator, or a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* comprising incubating pine cells of the subgenus *Pinus* with Agrobacterium eradicating Agrobacterium from the pine cells after incubation with Agrobacterium, washing cells with a liquid wash culture medium comprising nutrients and an osmoticum, selecting transformed cells, culturing said transformed cells to produce transgenic somatic embryos and germinating said transgenic somatic embryos to produce transgenic plants.

Applicants disclose a method for regenerating transformed plants of pine of the genus *Pinus* subgenus *Pinus* which is outlined on pages 23-45 of the specification and will not be repeated here. It is noted that DCR media is used in all steps of the claimed method.

Applicants claims are drawn to washing the pine cells in any medium comprising any nutrients and an osmoticum but Applicants state in the specification that the liquid medium used to wash the cells is similar in composition to the gelled medium on which the pine tissue is grown except that the gelling agents and any adsorbing components may be omitted (page 13, lines 24-27).

The state-of-the-art teaches that media components are important for a successful tissue culture procedure. Handley, III (January 1999, U.S. Patent Number 5,856,191) teach culture media used in pine somatic embryogenesis culture processes are key components and that the

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culture media comprises six groups of ingredients: inorganic nutrients, vitamins, organic supplements, a carbohydrate source, phytohormones and activated carbon.

Applicants also state that the phytohormones used in conifer embryogenic systems have traditionally been an auxin, and a cytokinin for the culture initiation and maintenance steps and ABA for embryo development (column 3, lines 47-49 and lines 57-65). In addition, Applicants disclose “ It has been observed that in a number of experiments using Agrobacterium transformation methods, that ABA is important in order to obtain transformed embryogenic masses from certain embryogenic lines of some elite lines and hybrids of Southern yellow pines” (page 16, paragraph 48).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through all the non-exemplified media, and all the non-exemplified steps that are encompassed by Applicants’ broad claims, for the purpose of finding a medium and additional steps that are required to regenerate transgenic plants of pine of the genus *Pinus* subgenus *Pinus*.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Handley, III et al (February, 1996, U.S. Patent Number 5,491,090).

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The claims are drawn to a method for pine tissue culture comprising culturing pine cells of the genus *Pinus* subgenus *Pinus* on a support membrane placed over a gel medium, or wherein the gel medium comprises tissue culture medium constituents, or wherein the cells are plated onto said support prior to culturing.

Handley, III et al discloses a tissue culture method for Pines, which includes pines in the genus *Pinus*, subgenus *Pinus*, comprising culturing said pine cells on a support membrane, and placing the support membrane on a solid medium (See column 26-28, claims 1-26, in particular claim 9; and column 8, lines 18-22) and as such, Handley, III et al anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 39-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levee et al (1999, *Molecular Breeding* 5:429-440) in view of Handley, III et al (February, 1996, U.S. Patent Number 5,491,090).

The claims are drawn to a method for minimizing damage to transformed cells of pine of the genus *Pinus* subgenus *Pinus* following infection by *Agrobacterium* comprising washing

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transformed cells in a liquid culture medium comprising nutrients and an osmoticum, plating said cells on a support membrane, resuspending said cells in a liquid culture medium and recovering cell, or wherein the washing and plating steps are repeated between 2 and 10 times, or wherein the wash is carried out for between half an hour to overnight or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Because Applicants have not defined “minimizing damage”, or have not included a comparative basis, the Office interprets the method to be one of a method of tissue culture involving resuspending and plating cells.

Levee et al disclose resuspending transformed pine cells following infection with *Agrobacterium* in a liquid 1/2LM and collecting the cells on a support membrane.

Levee et al do not disclose cells of pine of the genus *Pinus* subgenus *Pinus*, or repeated plating and resuspending said cells in a liquid culture medium, or wherein said plating and resuspending is repeated between 2 and 10 times, or wherein each wash is carried out for between half an hour to overnight or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Handley, III et al disclose a method of tissue culture for pine cells of the genus *Pinus* subgenus *Pinus* in which cells are suspended in liquid culture medium followed by collecting said cells on a support membrane (column 8, lines 18-22).

Given the recognition of those of ordinary skill in the art the value of culturing transformed pine cells comprising a method in which cells are resuspended and plated on a support membrane as taught by Levee et al, it would have been obvious to one of ordinary skill in the art to use the method of Levee et al and to modify said method by incorporating the

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method of Handley, III et al in which cells are placed in a liquid culture medium and then are gathered on a support membrane so that the cells do not have to be manipulated individually. It would have been obvious to optimize this method by optimization of process parameters by varying the number of times the cells are plated and gathered on a support membrane and by varying the time the cells are resuspended in a liquid culture medium or using a support membrane made from different polymers which include, polyester, polypropylene, or a liquid permeable fluoropolymer fabric; using a filter paper absorbed with a the liquid medium.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

8. Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handley, III et al (February, 1996, U.S. Patent Number 5,491,090).

The claims are drawn to a method for pine tissue culture comprising culturing pine cells of the genus *Pinus* subgenus *Pinus* on a support membrane placed over a gel medium, or wherein the gel medium comprises tissue culture medium constituents, or wherein the cells are planted onto said support prior to culturing, or wherein the layer is a liquid medium, or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

The teachings of Handley, III et al have been discussed above.

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Handley, III et al do not teach the layer is a liquid medium, or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Given the recognition of those of ordinary skill in the art the value of a pine tissue culture method for pine propagation comprising of culturing pine cells of the genus *Pinus* subgenus *Pinus* on a support membrane placed over a gel medium, or wherein the gel medium comprises tissue culture medium constituents, or wherein the cells are planted onto said support prior to culturing as taught by Handley, III et al, it would have been obvious to optimize this method by optimization of process parameters that would not confer patentable distinction on the claimed invention. The optimization of process parameters process involves placing the support membrane over a liquid layer of culture medium or using a support membrane made from different polymers which include, polyester, polypropylene, or a liquid permeable fluoropolymer fabric; using a filter paper absorbed with a the liquid medium.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

9. Claims 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levee et al (1999, Molecular Breeding 5:429-440).

The claims are drawn to a method for selecting transformed cells of pine of the genus *Pinus* subgenus *Pinus* comprising culturing said cells subsequent to transformation on a support membrane placed over a gel medium, contacting said cells with the selection medium and

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selecting transformed cells, or wherein said selection agent is contained in said medium or wherein said selection agent is contained in a layer and said support membrane is placed over said layer which is positioned on said gel medium, or wherein said layer is liquid medium, or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Levee et al disclose a method of selecting transformed pine cells subsequent to transformation by culturing the transformed cells on filter paper, which is a support membrane, and wherein the filter paper was placed on a selection medium comprising kanamycin (page 431, right column).

Levee et al do not teach selection of cells of pine of the genus *Pinus* subgenus *Pinus*, or wherein the selection agent is placed in a layer which is positioned over a gel medium, or a layer which is liquid, or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Given the recognition of those of ordinary skill in the art the value of selecting transformed cells subsequent to transformation comprising placing transformed cells on a support membrane which is then placed in contact with a medium comprising a selection agent as taught by Levee et al, it would have been obvious to optimize this method by optimization of process parameters that would not confer patentable distinction on the claimed invention. The optimization of process parameters process involves placing the support membrane over a liquid layer of culture medium or placing the support membrane on a layer (e.g. liquid) which is placed

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on a gel medium, or using a support membrane made from different polymers which include, polyester, polypropylene, or a liquid permeable fluoropolymer fabric or using a filter paper absorbed with a the liquid medium and selection agent. The Office contends this method is not restricted to a particular type of plant cell and choosing which plant cell to use is a design choice. Therefore, choosing one pine over another, i.e., *Pinus strobes* over a pine cell from the genus *Pinus* subgenus *Pinus* does not carry patentable weight.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

10. Claims 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levee et al (1999, Molecular Breeding 5:429-440).

The claims are drawn to a method for eradicating *Agrobacterium* from cells of pine of the genus *Pinus* subgenus *Pinus* comprising culturing said cells on a support membrane over a layer containing an eradicator, said layer positioned in or over a gel medium and recovering cells free of *Agrobacterium*, wherein said layer is a liquid medium, or wherein said layer is gelled medium, or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Levee et al teach eradicating *Agrobacterium* from pine cells subsequent to transformation comprising placing said cells on a support membrane which is placed on a gelled medium comprising cefotaxime to inhibit growth of bacterial cells (page 431, right column). The Office

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interprets “inhibiting growth of bacterial cells” to mean that bacterial cells were killed or eradicated. In addition, Applicants disclose that cefotaxime is an example of an eradicator (page 14, paragraph 43).

Levee et al do not teach eradicating *Agrobacterium* from cells of pine of the genus *Pinus* subgenus *Pinus*, or wherein the eradicator is placed in a layer which is positioned in or over a gel medium, or a layer which is liquid, or wherein said layer is a filter paper with a liquid medium absorbed therein, or wherein said support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric.

Given the recognition of those of ordinary skill in the art the value of eradicating *Agrobacterium* from pine cells subsequent to transformation comprising placing transformed cells on a support membrane which is then placed in contact with an eradicator as taught by Levee et al, it would have been obvious to optimize this method by optimization of process parameters that would not confer patentable distinction on the claimed invention. The optimization of process parameters process involves placing the support membrane over a layer containing an eradicator wherein said layer is positioned in or over a gel medium, or wherein said layer is a layer of liquid medium or using a support membrane made from different polymers which include, polyester, polypropylene, or a liquid permeable fluoropolymer fabric or using a filter paper absorbed with the liquid medium and eradicator absorbed therein. The Office contends this method is not restricted to a particular type of plant cell and choosing which plant cell to use is a design choice. Therefore, choosing one pine over another, i.e., *Pinus strobus* over a pine cell from the genus *Pinus* subgenus *Pinus* does not carry patentable weight.

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Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Response to Applicants' Remarks

Applicants' remarks and 132 Declarations are centered around the use of the Levee et al reference that was used in a obvious rejection of claims 1-9, 11-43 and 45-62 made in the previous non-final office action mailed 4/8/2004. The present office action only uses the Levee et al reference in obvious rejections for claims 39-43, 45, and 52-62. Applicants arguments are directed towards the use by Levee et al of water to wash transgenic pine cells and that there is no suggestion in Levee et al to use a liquid culture medium and no suggestion that use of a liquid culture medium would result in an enhanced transformation and regeneration of transformed embryogenic tissue of hard pines (page 16, top sentence and page 17, 3rd paragraph).

The Office contends that the Levee et al reference is not used in an obvious rejection for claims directed to method of enhanced transformation and regeneration of transformed embryogenic tissues of hard pines. The Office contends that the Levee et al reference is used in an obvious rejection for claims drawn to a method for selecting transformed cells of pine, a method for eradicating *Agrobacterium* from cells of pine and a method for minimizing damage to transformed cells of pine. In all cases, the Levee et al reference is not relied upon for teaching washing cell in water.

11. No claims are allowed.


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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
May 12, 2005


ELIZABETH MCELWAIN
PRIMARY EXAMINER